

Appln. No. 09/869,612
Amd. dated December 13, 2004
Reply to Office Action of June 15, 2004

Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

Claim 1 (Cancelled).

2 (Currently amended). A method for preparing a population of circulating CD34⁺ cells which regenerate hematopoiesis *in vivo*, comprising:

a) administering to a donor a composition comprising growth hormone or one of its derivatives having the activity of growth hormone or any factor inducing growth hormone release, simultaneously or separately with a composition comprising G-CSF, in an amount sufficient to enhance the mobilization or peripheralization effect of G-CSF to further increase in said donor the number of circulating CD34⁺ cells which regenerate hematopoiesis *in vivo* beyond that achieved by G-CSF alone; and

b) isolating a population of circulating CD34⁺ cells which regenerate hematopoiesis *in vivo* from the peripheral blood of said donor.

Claims 3 and 4 (Cancelled).

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5 (Previously presented). The method according to claim 2, wherein the increased number of CD34⁺ cells is more than 10, 25, 34 or 80 CD34⁺ cells per microliter of donor peripheral blood.

6 (Previously presented). The method according to claim 2, wherein the increased number of CD34⁺ cells is at least 2x10⁶, 4x10⁶, 5x10⁶, 6x10⁶, 8x10⁶, 15x10⁶ CD34⁺ cells per kilogram of donor body weight.

7 (Previously presented). The method according to claim 2, wherein the increased number of circulating CD34⁺ cells which regenerate hematopoiesis *in vivo* corresponds to about 500 or more CFU-GM per milliliter of donor peripheral blood.

8 (Previously presented). The method according to claim 2, wherein the increased number of circulating CD34⁺ cells which regenerate hematopoiesis *in vivo* corresponds to an increased level of CFU-C, CFU-Meg or BFU-E in donor peripheral blood.

9 (Previously presented). The method according to claim 2, wherein the increased number of circulating CD34⁺ cells which regenerate hematopoiesis *in vivo* substantially corresponds to a white blood cell count of about 1000 or more cells per microliter of donor peripheral blood.

10 (Previously presented). The method according to claim 2, wherein the increased number of circulating CD34⁺ cells which regenerate hematopoiesis *in vivo* corresponds to about 1x10⁵ or more GM-CFC per kilogram of donor or recipient body weight.

11 (Previously presented). The method according to claim 2, wherein the circulating CD34⁺ cells which regenerate hematopoiesis *in vivo* are CD34⁺/CD33⁺ cells and/or CD34⁺/CD38⁻ cells and/or CD34⁺/Thy-I cells and/or CD34⁺/Thy-I/CD38⁻ cells and/or bone-marrow stem cells and/or progenitor cells and/or long-term culture initiating cells (LTC-IC) and/or cells that fulfill self renewal potential and/or cells that fulfill pluripotential characteristics and/or cells that initiate long term bone marrow culture and/or cells that can generate multiple cell lineages.

12 (Previously presented). The method according to claim 2, wherein the target number of circulating CD34⁺ cells which regenerate hematopoiesis *in vivo* is at least 2x10⁴ LTC-IC per kg of donor or recipient body, about 2x10⁶ or more CD34⁺ cells per kilogram of donor or recipient body weight, about 4x10⁶ or more CD34⁺ cells per kilogram of donor or recipient body weight or about 8x10⁶ or more CD34⁺ cells per kilogram of donor or recipient body weight.

13 (Previously presented). The method according to claim 2, wherein the volume of blood processed in step (b) is in a range of about 30 to about 900 milliliters.

Claims 14-17 (Cancelled).

18 (Previously presented). The method according to claim 2, wherein growth-hormone or one of its derivatives or any factor inducing growth hormone release is administered in an amount between 20 to 50 $\mu\text{g}/\text{kg}$ of donor body weight, in an amount between 30 to 40 $\mu\text{g}/\text{kg}$ of donor body weight or in an amount of 33 μg per kilogram of donor body weight.

19 (Previously presented). The method according to claim 2, wherein the G-CSF is administered in an amount between 3 to 15 $\mu\text{g}/\text{kg}$ of donor body weight, in an amount between 4 to 12 $\mu\text{g}/\text{kg}$ of donor body weight or in an amount of around 5 or 10 μg per kilogram of donor body weight.

20 (Previously presented). The method according to claim 2, wherein the administration of Growth Hormone is made three times a day and the administration of G-CSF is made daily.

21 (Previously presented). The method according to claim 2, wherein the administration of said composition is made

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by parenteral, subcutaneous, intravenous, intramuscular,
intraperitoneal, transdermal or buccal routes.

22 (Previously presented). The method according to
wherein the administration of said composition is daily or three
times a day.

23 (Previously presented). The method according to 2,
wherein the administration of said composition is made over a
period of 5 days or over a period of 10 days.

24 (Previously presented). The method according to
claim 2, wherein the administration begins around 7 days after
the beginning of a chemotherapeutic treatment or around 2 days
after the end of a chemotherapeutic treatment.

25 (Previously presented). The method according to
claim 2, wherein the growth hormone is a recombinant growth
hormone.

26 (Previously presented). The method according to
claim 2, wherein the growth hormone is human growth hormone.

Claims 27-55 (Cancelled).

56 (Previously presented). The method according to
claim 2, wherein said growth hormone or one of its derivatives or

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any factor inducing growth hormone release is administered at a different time than said composition comprising G-CSF.

57 (Previously presented). The method according to claim 2, wherein said growth hormone or one of its derivatives or any factor inducing growth hormone release is administered simultaneously with said composition comprising G-CSF.